Claims 1, 8, 14, 18, 31, 38, 39 are pending. Claims 1, 8, 38 have been amended. Claim 39 has been cancelled.

Because the amendments do not introduce any new matter, Applicant respectfully requests that the amendments be entered.

Rejections Under 35 U.S.C. § 103(a)

The Examiner asserts that claims 1, 8, 14, 18, 31, 38, 39 are rejected under 35 U.S.C. § 103(a) for the reasons previously set forth in Paper No. 17, Sections 3-4, pages 2-6 and Paper No. 13 as cited in Paper No. 17 (i.e., as unpatentable over U.S. Patent No. 4,598,089 in view of Moloney (Livestock Production Science, 1995, 42:239-245), Flint (Proceedings of the Nutrition Society, 1992, 51:433-439), Ohkaru et al. (Clin. Chim. Acta (1989) 182:295-300) or JP 02150294, U.S. Patent No. 5,585,098, U.S. Patent No. 5,080,895—with Coleman (U.S. 5,585,098) withdrawn in Paper 17 as drawn to administration to non-ruminant animals).

Legal Standards

An obviousness analysis requires that the claimed invention be (a) considered as a whole, (b) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination, and (c) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention, and (d) reasonable expectation of success is standard with which obviousness is considered. MPEP 2141.

A prima facie case of obviousness by the Examiner requires establishment of 3 criteria:
(1) suggestion or motivation in the references themselves or in the art generally available to one of ordinary skill, to modify or to combine reference teachings,
(2) reasonable expectation of success, and
(3) prior art reference(s) must teach or suggest all the claim limitations.
MPEP 2142.

As for determination of criteria (1), there are 3 possible sources of motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. MPEP 2143.01.

As for criteria (2), the proposed modification cannot render the prior art unsatisfactory for its intended purpose. MPEP 2143.01. Nor can the proposed modification change the principle of operation of a reference. MPEP 2143.01.

As for criteria (3), all claim limitations must be considered when making a determination of obviousness, whether the limitations are indefinite or whether they find support in the original specification. MPEP 2143.03.

Combining or substituting equivalents known for the same purpose is permissible to establish prima facie obviousness (MPEP 2144.06), however, the items must actually be "equivalents" and must actually be known for the "same purpose." The equivalency must be recognized in the prior art and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. MPEP 2144.06. The selection of a known material based on its suitability for its intended use can support a prima facie obviousness determination. MPEP 2144.07. However, Examiner has to show support for the material's suitability for its intended use.

Assuming an Examiner has made a prima facie case and the applicant is required to rebut it, any decision to make or maintain a rejection in the face of all the evidence must show that it was based on the totality of the evidence. Facts established by rebuttal evidence must be evaluated along with the facts on which the conclusion of obviousness was reached, not against the conclusion itself. MPEP 2142.

A prima facie case of obviousness can be rebutted by evidence of superior or unexpected results. MPEP 2144.09.

U.S. 4,598,089 (Hadvary et al.) (U.S. '089)

U.S. Patent No. 4,598,089 (Hadvary et al.) discloses leucine derivatives (N-formylleucine derivatives) which inhibit pancreatic lipase. Lipstatin and tetrahydrolipstatin are lactones. These are chemical drug (non-immunological) compounds rather than immunological compounds. The method of '089 is a method of preventing obesity in a mammal comprising "administering to the mammal a compound of the [invention] in an amount effective in preventing obesity by inhibiting pancrease lipase" (claim 17). The reference does not disclose by what mechanism the drug is able to inhibit pancreatic lipase.

Moloney (Livestock Production Science, 1995, 42:239-245)

Moloney discloses a review of decreasing body fat accretion by destroying existing fat cells (adipocytes) by cytotoxic antibodies (p. 240, second paragraph). This is the destruction of existing body fat and has nothing to do with ingested fats. This targeted existing body fat may have been produced from ingestion of any type of food material. Passive immunization of

laboratory animals by Flint et al. and Futter and Flint (antibodies to adipose tissue plasma membranes) were found to be cytotoxic at high concentrations in the presence of complement (p. 240, section 3). Subcutaneous administration of antibodies had a greater effect on subcutaneous fat than internal fat and the opposite was seen with antibodies administered i.p. (therefore, the effect was generally localized to administration site) (p. 240, section 3). Later researchers had less consistent results (e.g., Hu et al.) (p. 240, section 3 last 6 lines). Passive immunization of meat animals was also disclosed in this review article (p. 240-242, section 4). Lambs immunized s.c. or i.v. showed some decrease in adipose tissue locally but **no significant effect** on carcass fat content (p. 242, col. 1, lines 6-7). Other researchers (Thorton and Tume, 1987) **failed** to detect a reduction in adipose tissue in sheep (p. 242, col. 1, lines 14-15. Antibodies to chicken adipose tissue which were cytotoxic in vitro **did not** reduce fat in vivo (p. 242, col. 1, lines 20-21). Subcutaneous immunization of pigs resulted in localized reduction of backfat at the site of injection (p. 242, col. 1, lines 23-25). None of the passive immunization studies were conducted with oral antibodies. Active immunization (p. 242, section 5) was discussed as possibly producing detectable antibody titers and possibly showing a decrease in adipose cell number and/or localized adipose tissue. In addition to the **site specificity** of the adipose cytotoxicity, an **adverse side effect** of this cytotoxicity immune response was found to be lysis of desired cells (i.e., erythrocytes and liver tissue).

Combination of '089 and Moloney or Modification of '089 with Moloney

The present invention claims a method of inhibiting lipase so as to reduce fat absorption by feeding an antibody that binds lipase in the GI tract, i.e., reduce absorption of fat from ingested fat, since the only fat absorbed in the GI tract is ingested fat. The antibody in the present application does nothing to the fat itself (either ingested or body fat). The antibody

instead affects the lipase activity, and as a result, absorption of the fat. This is an entirely different mechanism and occurs at an entirely different location than the Moloney reference. Moloney addresses the source of the ingested fat (animal flesh to be ingested) ("ingestee") whereas the present invention addresses the "ingestor"/consumer of the fat. The Moloney antibodies affect body fat, the present antibodies affect lipase (enzyme) which breaks down ingested fat. A compound (chemical or immunological) which is directed toward fat would not be expected to have any function against a proteinaceous enzyme. Fats and proteins have entirely different chemical structures. A compound which would lyse a fat would not be expected to have an effect on an enzyme. Further, the results of the various studies reviewed in Moloney show contradictory results (some fat reduction, some no significant effect on fat in vivo). The contradictory results may teach away from using an immunological method of lysing body fat, let alone any effect on ingested fat. Still further, ingested fat may not be formed into fat once absorbed and utilized by the body, it may be used as energy, only when excess calories are consumed are ingested foodstuffs converted again into fat in the body.

One of skill in the art would **not** be motivated to modify the method of '089 by substituting antibodies to adipose tissue plasma membranes (reduce/lyse existing fat in living animal tissue) disclosed in Moloney for a chemical which has an **entirely different function (entirely different purpose) and entirely different mechanism** (inhibiting pancreatic lipase which prevents breakdown and absorption of ingested fats). Further, effective oral administration of a chemical is less surprising than effective oral administration of antibodies since the body normally breaks down proteinaceous substances during their travel through the GI tract. The orally ingested antibodies must survive the mouth, esophagus, and stomach before arriving at the duodenum. Still further, the indicated adverse side effects of the antibodies in

Moloney would likely steer one of skill in the art away from a similar immunological method. In addition, since the '089 method is directed to a mammal which ingests foods containing fat and Moloney is directed to the source of the fatty food, one of skill in the art would not be motivated to combine these references. The fat in Moloney is not affected by lipase since it is in the carcass of the animal, lipase does not occur in the carcass of the animal. Inhibition of lipase in Moloney would not effect the adipose tissue existing in the animal. Lysing of adipose tissue in '089 mammals would only affect the existing fat and would have no effect on the fat ingested. Substituting the compound of '089 for the antibodies of Moloney would render Moloney unsatisfactory for its intended purpose. Substituting antibodies of Moloney for the compound of '089 would likewise render '089 unsatisfactory for its intended purpose. Either of these combinations or modifications would also change the principle of operation of each of the references.

There is no expectation of advantage by combination or modification of the references found expressly or impliedly in the references cited by the Examiner. MPEP 2144.

None of the three obviousness criteria are met with this combination/modification.

Flint (Proceedings of the Nutrition Society, 1992, 51:433-439)

Flint (review article) discloses methods for **decreasing fat content in the food** source, **or** in ingestor after excess energy from food has been converted into **body fat**, using lipolytic agents, much like Moloney, **rather than** the **utilization** end of food. Speculation regarding immunoneutralization of growth hormone (GH), insulin, gastric inhibitory polypeptide (GIP), glucagons-like peptide-1 are disclosed (p. 433-434). However, the article points out that immunoneutralization of GH has provided mixed results, immunization against somatostatin "**never achieved** the reduction in fat content," and direct immunization of insulin has proved to

be "**extremely difficult**" (p. 434, emphasis added). Immunization against GIP showed some reduction in insulin response in rodent but "**no** long-term consequences on adipose tissue metabolism" were reported (p. 435, emphasis added). Flint also discloses articles regarding immuno-enhancement (enhancing activity of hormones such as GH) (p. 435). Immuno-mimicry is disclosed but does not disclose anything regarding adipose tissue nor utilization of fat (p. 435). Immunocytotoxicity is disclosed (p. 436), an approach of producing antibodies capable of binding to and destroying adipocytes (process of Moloney). Flint notes that this approach is "conceptually different from virtually all other approaches to reduce body fat (except lipectomy) since it aims to remove cells rather than regulate their metabolism" (p. 436). Flint further notes "[a]ctive immunization ... involves and autoimmune response and this is typically **difficult** to evoke and **virtually impossible** to regulate (p. 437, emphasis added). Also, "antibodies may have immunoneutralizing and immunoenhancing properties" resulting in "**contradictory** results" (p. 437, emphasis added). No disclosure of oral administration of immunological material is found in Flint's review.

Combination of '089 and Moloney and Flint or Modification of '089 with Moloney and Flint

Flint does **not** discuss the absorption and utilization of fat in food. Again, this reference would not be combined with '089 (as Moloney would not) since they are directed to entirely different locations, mechanisms, and the unlikely substitution of an immunological agent for a drug agent. The failing results teach away from using an immunological method of controlling body fat, let alone any effect on ingested fat. Ingested fat may not be formed into fat once absorbed and utilized by the body. Flint further teaches away from use of immunological methods for lysis of fat tissue due to the disclosed failures in the Flint review, if lysis of fat were the mechanism of interest in the present case, which it is not. Flint also points out the generally

difficult work with antibodies and delivery thereof. **Flint discloses many failures of immunological methods, especially non-oral administrations. Oral delivery is known by one of skill in the art, and would be expected, to be even more difficult to control than other modes of delivery.**

One of skill in the art would **not** be motivated to modify the method of '089 by substituting antibodies to adipose tissue plasma membranes (reduce/lyse existing fat in living animal tissue) disclosed in Moloney or antibodies disclosed in Flint to reduce body fat for a drug which has an **entirely different function (entirely different purpose) and entirely different mechanism** (inhibiting pancreatic lipase which prevents breakdown and absorption of ingested fats). Effective oral administration of a drug is less surprising than effective oral administration of antibodies since the body normally breaks down proteinaceous substances during their travel through the GI tract. The orally ingested antibodies must survive the mouth, esophagus, and stomach before arriving at the duodenum. Further, the indicated failures of the antibodies in Flint and failures and adverse effects of Moloney would likely steer one of skill in the art away from similar immunological methods. In addition, since the '089 method is directed to a mammal which ingests foods containing fat and Moloney and Flint are directed to the source of the fatty food, one of skill in the art would not be motivated to combine these references. The fat in Moloney or Flint is not affected by lipase since it is in the carcass of the animal, lipase does not occur in the carcass of the animal. Inhibition of lipase in Moloney of Flint would not effect the adipose tissue existing in the animal. Lysing of adipose tissue in '089 mammals would only affect the existing fat and would have no effect on the fat ingested. Substituting the compound of '089 for the antibodies of Moloney or Flint would render Moloney and Flint unsatisfactory for their purposes. Substituting antibodies of Moloney or Flint for the compound of '089 would

likewise render '089 unsatisfactory for its purpose since the antibodies would have no effect on ingested fat (even if surviving long enough).

There is no expectation of advantage by combination or modification of the references found expressly or impliedly in the references cited by the Examiner. MPEP 2144.

None of the three obviousness criteria are met with this combination/modification.

Ohkaru et al. (Clin. Chim. Acta (1989) 182:295-300)

Ohkaru et al. abstract discloses two monoclonal antibodies (MAbs) raised against pancreatic triacylglycerol lipase for use in an immunosorbent enzyme assay or competitive binding enzyme immunoassay. One partially inhibited the lipase and bound enzyme-labelled lipase competitively; the other did not inhibit the lipase nor bind competitively.

There is no disclosure of in vivo activity of the MAbs, no disclosure of administration of the MAbs to any animal, and no disclosure of oral administration of the MAbs in this reference. There is no indication that the particular MAbs would retain its activity or be effective if used in vivo or orally. There is no indication in the art generally that all MAbs will work in vivo or orally. There is also no indication of how the MAbs were raised.

Combination of '089 and Moloney and Flint and Ohkaru or Modification of '089 with Moloney and Flint and Ohkaru

Even if one could use the overly simplistic logic that a drug that inhibits pancreatic lipase and an antibody which inhibits pancreatic lipase are components that are functional equivalents, the equivalency must be recognized in the prior art. MPEP 2144.06. The Examiner has not provided any factual evidence or technical logic that these two agents are recognized in the art as equivalents for the same purpose. There is no evidence of art recognized equivalence of

substituting an antibody for a drug. Besides one agent being a drug and the other being an antibody, this proposed substitution is further complicated by the recognition in the art that in vivo vs in vitro delivery and activity of agents may differ and oral vs. other modes of administration may provide differences in activity of agents. Flint and Moloney, for example, would strongly indicate/suggest that there are differences between antibody results in vitro and in vivo and that all antibodies are not expected to work in vitro or in vivo. Flint and Moloney also demonstrate differences potentially resulting from modes of administration, e.g., localized body fat lysing. Therefore, in addition to there being no suggestion or motivation to make the combination/substitution/modification, there is no expectation of success in making such a substitution/modification. There is no expectation of advantage by combination or modification of the references found expressly or impliedly in the references cited by the Examiner. MPEP 2144. Moloney and Flint, if they can be generalized to antibody use (and not just the specific antibodies/uses disclosed in the references), teach away from substituting more unpredictable antibodies for the drug of '089.

Also, the Examiner has not shown teaching or suggestion for all claim limitations.

JP 02150294 (Kajita et al.)

JP 02150294 discloses a monoclonal antibody reacting with human pancreatic lipase without hindering lipase activity and that which hinders the enzymatic activity of human pancreatic lipase. A method for determining the presence of human pancreatic lipase is disclosed which involves immobilizing an antibody on a solid phase, a sample, and an enzyme-labeled antibody to the immobilized antibody. There is no disclosure involving in vivo or oral use and no details regarding the anti-human pancreatic lipase enzymatic activity-hindering monoclonal antibody. The antibodies of JP '294 are prepared from a fusion "hybridomer"

formed between antibody producer cells and bone marrow cells, the hybridomer being cloned, and the clones producing antibodies. At most this reference shows existence of antibodies which may hinder activity of human lipase to some extent in vitro. Of the 115 clones created, 10 (8.7%) blocked the enzyme activity of the lipase, 13 (11.3%) blocked to a moderate extent, and 12 (10.4%) weakly blocked it (total of 30% of all produced antibodies showing any hindering activity toward lipase). Of these only 7 were established through 3 cycles of cloning which strongly blocked the lipase activity. The anti-human pancreatic enzyme blocking MAbs of JP '294 couple/react with the lipase antigen molecules while leaving the lipase enzyme activity totally unblocked (see "Effect of the Invention").

Combination of '089 and Moloney and Flint and JP 02150294 or Modification of '089 with Moloney and Flint and JP 02150294

The JP reference has the same problems as discussed above regarding Ohkaru. Even if one could use the overly simplistic logic that a drug that inhibits pancreatic lipase and an antibody which inhibits pancreatic lipase are components that are functional equivalents, the equivalency must be recognized in the prior art. MPEP 2144.06. The Examiner has not provided any factual evidence or technical logic that these two agents are recognized in the art as equivalents for the same purpose. Besides one agent being a drug and the other being an antibody, this proposed substitution is further complicated by the recognition in the art that in vivo vs in vitro delivery and activity of agents may differ and oral vs. other modes of administration may provide differences in activity of agents. The JP reference process is a totally ex vivo method and no expectation of in vivo success is desired or indicated. Flint and Moloney, for example, would strongly indicate/suggest that there are differences between antibody results in vitro and in vivo and that all antibodies are not expected to work in vitro or in

vivo. Therefore, in addition to there being no suggestion or motivation to make the combination/substitution/modification, there is no expectation of success in making such a substitution/modification. There is no expectation of advantage by combination or modification of the references found expressly or impliedly in the references cited by the Examiner. MPEP 2144. Moloney and Flint, if they can be generalized to antibody use (and not just the specific antibodies/uses disclosed in the references), teach away from substituting more unpredictable antibodies for the drug of '089.

Combining this with the other references would render the JP '294 antibody unsuitable for the JP reference's purpose. Substituting the drug of '089 in JP '294 would not produce an assay for determination of lipase. Modifying U.S. '089 by substituting the antibody of the JP reference for the drug of '089 has the same problems as Moloney and Flint and Ohkaru. Also, there is no evidence that the time period required for the JP '294 reaction between the antibody and lipase is available in vivo in the GI tract. Further, the JP reference translation states "the anti-human pancreatic enzyme activity blocking [MAbs]" of JP '294 couple/react with the lipase antigen molecules locating the atomic epitopes "**apart from the enzyme activity sites while leaving the lipase enzyme activity totally unblocked**" (see "Effect of the Invention," 1st paragraph, lines 4-8). This implies that the antibodies of the JP reference do not bind with the lipase to inhibit the activity.

Also, the Examiner has not shown teaching or suggestion for all claim limitations.

U.S. 5,585,098 (Coleman) (U.S. '098)

It appears that the **U.S. 5,585,098** Coleman reference was **withdrawn** in Paper 17. **However**, Coleman does disclose some things about the **state of the art** the Examiner should consider. U.S. '098 discloses a method for lowering somatic cell count in the milk of a lactating

ruminant. IgY ("yolk immunoglobulin")/IgG Abs are obtained from the egg of a hen which has been actively immunized against one or more mastitis-causing pathogenic organisms by injection with an immunogen containing immunogenic determinants specific to elicit such antibodies. The antibodies are administered orally to a ruminant suffering from or for the prevention of mastitis caused by the pathogenic organism.

The patent states that in order to be effective against pathogenic agents, specific antibodies must reach their target immunologically active. "Heretofore it has never been shown or even suggested that antibody administration by the oral route could be targeted to favorably interfere with specific pathogens or substances in a site remote to the intestine." IgY only is contained in the yolk, and IgM and IgA are found only in the white. The newly discovered systemic effect of IgY relates to the absorption or translocation of **fragments** of orally administered antibody from the intestine into circulation. The IgY molecule is **disassembled** by naturally occurring enzymes in the intestine into binding fragments, which comprise peptides of the highly variable portion, Fab chain, of the terminal domain of the antibody. The constant, of Fc, portion of IgY is left in the intestine.

Therefore, **this reference shows** that the IgY **orally** administered in '098 **are** actually **broken down** in or on the way to the intestine. The particular antibodies in '098 happen to maintain the desired effect because the variable portion of the antibody makes it to the desired location in the body and the variable portion happens to be effective against the pathogens of interest. There is no knowledge generally in the art that an antibody will remain intact during passage through the GI tract, that a fragmented antibody will retain activity, that a fragment that retains activity will be in a desired location, nor that can this antibody or fragment behavior be predicted ahead of time. **This further demonstrates support** for the thought processes found in

Dr. Atkinson's Declaration which express surprise as to the retained activity of the antibodies in the present invention and **teaches away from a reasonable expected success**.

U.S. 5,080,895 (Tokoro) (U.S. '895)

U.S. 5,080,895 discloses a substance which contains a specific antibody or specific transfer factor-like component produced from the yolk or albumens or both of eggs of a hen which has been immunized against a selected antigen such as a pathogenic bacteria. The substance can be orally administered to animals affected by an intestinal infectious disease.

This references adds nothing more than Coleman nor disputes those issues illustrated in Coleman regarding breakdown of antibodies. It is implied that the specific antibody activity of '895 may survive to the intestine at least by Ig fragment (col. 3, line 62).

Declaration by Dr. Atkinson

The Examiner states that the Declaration of Dr. Atkinson is based on the assumption that "the antibodies reach the duodenum of the gastrointestinal tract and still be active to inhibit pancreatic lipase" and that Dr. Atkinson is arguing limitations not recited in the claims as presenting constituted. The Examiner further asserts that the claimed invention does not require that pancreatic lipase be inhibited in the duodenum.

Applicant respectfully points out the following basic physiology and biochemistry to the Examiner. A zymogen of pancreatic lipase is synthesized in the pancreas and this zymogen is secreted into the duodenum where it is activated into pancreatic lipase. Therefore, by virtue of basic physiology this so-called limitation is the earliest location in which an orally administered antibody could contact a pancreatic lipase in the GI tract. "Lipases are a family of hydrolytic enzymes that release fatty acids from triacylglycerols. Pancreatic lipase is synthesized in the pancreas as a zymogen and secreted into the duodenum via the pancreatic duct. Upon entrance

into the duodenum, ..., the zymogen is activated through hydrolysis of a specific peptide bonds by trypsin." A zymogen is a proenzyme (precursor to active enzyme. Zymogens are activated by proteolytic enzymes called proteinases. Rawn, Biochemistry, 1989, Burlington, NC, p. 424. The Examiner has provided no reasoning or evidence that pancreatic lipase exists in other locations "in the GI tract" (which is a limitation of the claims) that an orally administered antibody could come into contact with pancreatic lipase.

For the reasons set forth above, the combined teachings of the cited references fail to render the claimed invention obvious. Therefore, applicant respectfully requests withdrawal of the rejection and allowance of the pending claims to issue.

Rejections Under 35 U.S.C. § 132

The Examiner asserts that the amendment filed October 1, 2001 (Paper No. 26) is objected to under 35 U.S.C. 132 because it introduces new matter into the specification, specifically:

the phrases "post suckling" and "non-ruminant mammals" are asserted to have no support in the specification or claims as originally filed and

the phrase "by inhibiting or binding lipase the ingested fat will not be absorbed" is asserted to have no support in the specification or claims as originally filed.

The Examiner asserts that the term "binds" is recited in claim 3 as originally filed, but that the term is drawn to antibody binding to lipase which inhibits its activity in the GI tract.

The Applicant respectfully traverses this rejection and makes no admissions of acceptance of the reasoning. Applicant respectfully points out that the test for new matter is not one of verbatim existence of text in the original application. However, in order to expedite prosecution, the Applicant authorizes the Examiner to cancel that material which the Examiner regards as "new matter" as legally defined.

Rejections Under 35 U.S.C. § 112 1st paragraph

Claims 1, 8, 14, 18, 31, 38, and 39 were rejected under 35 U.S.C. 112, first paragraph as the specification was asserted to not contain a written description of the claimed invention. The Examiner asserts that the limitations of "post sucking mammal" [sic] recited in claim 1 and "non-ruminant" recited in claim 8 and also recited in claims 38-39 have no clear support in the specification and the claims as originally filed.

The Applicant makes no admissions to acceptance of Examiner's rejection. However, in order to expedite prosecution, the Applicant has amended claims 1, 8, and 38. This rejection should now be withdrawn.

Claims 1, 8, 14, 18, 31, 38, and 39 were rejected under 35 U.S.C. 112, first paragraph as the specification was asserted to not contain a written description of the claimed invention. The Examiner asserts that the limitations of "antibody that binds to pancreatic lipase" in the GI tract has no clear support in the specification and the claims as originally filed. Examiner states that a review of the originally filed specification reveals support for an "antibody that binds to lipase" in originally filed claim 3 but no support for the specifically claimed pancreatic lipase binding.

Applicant respectfully traverses this rejection. Page 3, line 8 of the specification states "[l]ipase, an enzyme produced by the pancreas...." Since other types of lipase are not produced by the pancreas and only pancreatic lipase is produced by the pancreas, one of skill in the art would know that the references to lipase in the specification and claims refer to pancreatic lipase. Further, on p. 4, lines 1-2 is a description of an antigen, swine pancreatic extract that contains lipase, i.e., a pancreatic lipase. The antibody that would be produced against this antigen must accordingly be an antibody to a pancreatic lipase. Therefore, Applicant respectfully requests that this rejection be withdrawn.

Claims 38 and 39 were rejected under 35 U.S.C. 112, first paragraph as the specification was asserted to not contain a written description of the claimed invention. The Examiner asserts that the limitation of "immunizing a producer animal with pancreatic lipase to produce pancreatic lipase antibody" has no clear support in the specification and the claims as originally filed. Examiner states that a review of the originally filed specification reveals support for the present invention relating to a method for decreasing fat absorption by orally feeding chickens antibodies against lipase and the effectiveness of chicken antibodies has been reported. The specification is asserted to exemplify the preparation of the specific antibody against lipase by producing the antibody in 17-week old hens by injecting them with lipase.

The Applicant makes no admissions to acceptance of Examiner's rejection. However, in order to expedite prosecution, the Applicant has amended claim 38. This rejection should now be withdrawn.

Claims 38 and 39 were rejected under 35 U.S.C. 112, first paragraph as the specification was asserted to not contain a written description of the claimed invention. The Examiner asserts that the limitation of "altering the normal digestive process of a post-suckling mammal" has no clear support in the specification and the claims as originally filed. The Examiner states that a review of the originally filed specification reveals support for a method for decreasing fat absorption by orally feeding chicken antibodies against lipase.

The Applicant makes no admissions to acceptance of Examiner's rejection. However, in order to expedite prosecution, the Applicant has amended claim 38. This rejection should now be withdrawn.

Rejections Under 35 U.S.C. § 112, 2nd paragraph

Claims 38-39 were rejected under 35 U.S.C. 112, 2nd paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Examiner asserts that claims 38-39 are confusing because claim 38 recites the phrase "altering the normal digestive process of a post suckling mammal to inhibit the adsorption of fat." The Examiner further asserts that the claims are confusing because it is not clear whether the normal digestive process claimed is the absorption of fat or whether the normal digestive process refers to all of the processes of digestion that occur, including for example, cellular metabolism.

Claim 38 has been amended; this rejection should now be withdrawn. Claim 39 is dependent on claim 38 thus the rejection regarding this claim should be withdrawn as well.

Attached hereto is a marked-up version of the changes made to the specification and claims. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

The undersigned believes that a three month extension of time is necessary to make this Response timely. Payment in the amount of $460.00 for the extension of time is to be charged to a credit card and such payment is authorized by the signed, enclosed document entitled: Credit Card Payment Form PTO-2038. This amount is believed to be correct. Should this be in error, Applicant respectfully requests that the Office grant such time extension pursuant to 37 C.F.R. § 1.136(a) as necessary to make this Reply timely, and hereby authorizes the Office to charge any necessary fee or surcharge with respect to said time extension or any additional fees which may be required, or credit any overpayment to the deposit account of the undersigned firm of attorneys, Deposit Account 14-0629.

Respectfully submitted,

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David Thorpe

7-2-02
Date

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

Kindly replace the paragraph on p. 3, line 14-16 with the following:

Therefore, by inhibiting [or binding] lipase through binding the ingested fat will not be absorbed and the fat itself will be excreted.

IN THE CLAIMS

Please amend Claim 1 as follows:

1 (Amended Five Times). A method for inhibiting pancreatic lipase so as to reduce fat absorption in a [post-suckling] mammal by orally feeding said mammal an avian antibody that binds pancreatic lipase in the gastro-intestinal tract of said mammal to inhibit the fat-hydrolyzing activity of said pancreatic lipase.

Please amend Claim 8 as follows:

8 (Amended Four Times). The method of claim 1 [wherein said mammal is a non-ruminant and] wherein prior to the step of feeding said mammal said avian antibody, said antibody is produced in avian eggs.

Please amend Claim 38 as follows:

38 (Amended). A method of altering the absorption of fat [normal digestive process] of a [post-suckling] mammal to inhibit the absorption of fat, comprising the steps of immunizing an [producer] animal with pancreatic lipase to produce a pancreatic lipase antibody, and then orally administering said antibody to said [post-suckling] mammal to bind pancreatic lipase in its

gastro-intestinal tract and thereby inhibit the fat-hydrolyzing activity of said pancreatic lipase in said tract.

Please delete Claim 39.

[39. The method of claim 38 in which said post-suckling mammal is a non-ruminant.]